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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,902	10/01/2003	Kirk Matthew Schnorr	10274.200-US	8351

25908 7590 07/06/2005

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EXAMINER	
GEBREYESUS, KAGNEW H	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,902	SCHNORR ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-57* is/are rejected.

7)☐ Claim(s) *58 and 59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 10 line 13, " in particular up to 1000°C is unrealistic. For examination purposes the examiner it will be read as 100°C. In addition various letters are missing for some words in the specification, example page 5, line 3, page 7 line 32, page 8 line 1, page 31 title, page 42 line 1 pages 43 and 45 on the titles etc. Appropriate corrections are required.

Claim Objections

2. Claims 40-59 are objected to because of the following informalities: The abbreviation GH-61 must be written in full in the first instance. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 40-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 40-54 are directed to a genus of GH-61 polypeptides from any source naturally occurring or man made. The specification teaches the structure of GH-61 having the sequence of SEQ ID NO: 2, 4 and 6 represented from the family of GH-61 polypeptides. Moreover, the

specification fails to describe any other representative species by any identifying characteristics or properties other than a specific function of the polypeptide. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention i.e. all known and unknown GH-61 polypeptide from any source. The claims are drawn to a genus of GH-61 polypeptides from any source both naturally occurring and man made. Therefore, the claims recite to diverse genera defined by function only.

3. Claims 40- 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptides of SEQ ID NO: 2 and 4 and the method using the same to prevent staling of edible products, does not reasonably provide enablement for any GH-61 from any source (as encompasses by claims 40, 53) or any GH-61 polypeptide having 70% identity to an enzyme of SEQ ID NO: 2 or 4 (as encompassed by claims 54-57) and method of use thereof to prevent staling. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification does not enable any person skilled in the commensurate in scope with these claims.

Claims 40-53, 54-57 are so broad as to encompass any GH-61 from any source or any GH-61 polypeptide having 70% identity to an enzyme of SEQ ID NO: 2 or 4. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the large number of characterized and uncharacterized glycosyl hydrolase enzymes broadly encompassed

by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only three GH-61 polypeptides.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims 54-57 and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any GH-61 polypeptide with 70% identity to the polypeptides of SEQ ID NOS: 2, or 4 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting enzyme name activity; (B) the general tolerance of enzyme name to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any enzyme name residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any GH-61 polypeptide from any source (claims 40-53) or a variant of SEQ ID NO: 2 or 4 with an enormous number of amino acid modifications wherein up to 30% of the residues are altered from that of SEQ ID NOS: 2 or 4 (claim 54-57). The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of GH-61 polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Can any polypeptide having the coordinates as depicted in claim 54 suffice to identify a GS-61 polypeptide? The metes and bounds of this claim is not clear. Without specifying a point of reference for all GH-61 polypeptides (as encompassed by the claim) it is not possible to allocate the indicated coordinates.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 40-54 rejected under 35 U.S.C. 102(b) as being anticipated by Saloheimo et al, (1997) et al.

Saloheimo et al, disclose a glycosyl hydrolase family 61 polypeptide wherein the nucleotide sequence and encoded polypeptide sequence were submitted to GenBank with the accession no. Y11113.

Claims 40-54 rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al, (2001). Ito et al have disclosed another GH-61 polypeptide wherein the nucleotide and amino acid sequence was disclosed in GenBank accession no. AB055432 (2001) thus anticipating. These disclosures are two out of a number of GH-61 polypeptides disclosed prior to the disclosure in the instant application.

Claim Objections

Claims 58 and 59 are objected to for depending on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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